Food Safety Consultant Services
John Mason, DVM, MPH
301 East 64th Street
New York, NY 10021
Tel.: 212-628-1562 • Fax: 212-628-0026

August 8, 2000

TO: USDA/FSIS Docket Clerk - Docket No. 98-045N4
FDA Dockets Management Branch - Docket No. 00N-0504

I would like to make some comments on the "Current Thinking Papers on National Standards for Egg Safety" recently published jointly by FDA/FSIS. These comments are extensions of remarks that I made at the public meeting on the same topic in Washington, DC on July 31, 2000.

I would like to commend both agencies for giving the public the opportunity comment on their current thinking on egg safety.

According to the material distributed on July 31, 2000, the proposed rules for egg safety standards will be published in 2000, the final rules in 2001, to be implemented in 2002-2003, the on-farm standards by the FDA and the standards for egg packers and processors by the FSIS.

I feel that there is no need to wait until 2002-2003 to implement a suitable program for egg safety. The information necessary to mount a successful on-farm program was essentially available in 1992 and was being used by the Veterinary Services in its SE Control Program from 1992 to 1995, when the program was transferred to the FDA. Because of the subsequent curtailment of funds for the program and the lack of aggressive leadership, very little was done by Federal agencies between 1995 and 2000.

I would like to propose a series of actions which could be initiated almost immediately to get the SE control program back on track and pick it up where it was discontinued in 1995:

1. The FDA should ask the USDA Veterinary Services to administer the program, as it did from 1990-1995. This could very likely be done with its current personnel and could best function as an extension of the successful NPIP program.

2. Detailed standards for egg quality assurance (QA) programs should be established. This could be done most appropriately at the next meeting of the SE Committee of the USAHA in Birmingham, Alabama on October, 21', 2000.

3. Assistance and training should be provided to existing QA programs and to those wishing to start new programs.

00N-0504 C37

4. A USDA "Seal of Approval" should be available for use by QA programs that comply with the adopted QA standards of performance.

5. Services for monitoring and certification of QA programs should be provided, if they cannot be provided adequately by state agencies.

6. When necessary, laboratory services for QA programs should be provided, including a certification program for State and private laboratories.

7. The USDA, through its Agricultural Marketing Service, should assist producers who find it necessary to divert eggs from SE-positive flocks to pasteurization. This measure is crucial for the operation of an acceptable QA program. At the preset time, almost 30% of eggs produced in the U.S. are pasteurized for use as egg products. Many of the large egg producers operate their own "breaker" plants. Others have contracts with pasteurization plants. It should be possible for the AMS to work out some system whereby eggs that need to be sent for pasteurization by smaller producers could be purchased by AMS at market value and sent to "breaker" plants. This could become part of AMS's program for the purchase of agricultural products for the use of various Government programs.

8. VS/USDA should also carry out the traceback program for SE outbreaks, as it did successfully from 1990-1995.

* * *

I assume that the FDA intends to require mandatory compliance of all egg producers with some set of national standards for egg safety in 2001, with enforcement in 2002-2003. At the present time, some 60% of the egg produces are already utilizing some type of QA program, with some level of testing for SE. This accelerating use of these programs is largely responsible for the drop in SE incidence in humans in recent years. Active government sponsorship of voluntary QA programs, with the additional features listed above, over the next few years, should serve to lower SE rates even further, to the point where an expensive mandatory Federal program would not be necessary.

I am enclosing other comments I have made in the past in regard to egg safety.

Sincerely,

John Mason

John Mason, DVM, MPH

FOOD SAFETY CONSULTANT SERVICES
JOHN MASON, DVM, MPH
301 East 64th Street
New York, New York 10021
(212) 628-1562

February 4, 2000

Subject: Comments on "Action plan to eliminate Salmonella Enteritidis (SE) illness due to eggs"

To: The President's Council on Food Safety

I have reviewed the "Action Plan to Eliminate Salmonella Enteritidis (SE) Illness Due to Eggs" issued by the council on December 13, 1999. I would like to make some comments for the record. These comments are based on my experience as the Director of the USDA SE Control Program (1990-1994) and subsequently as a food safety consultant.

1. Generally, the Action Plan covers all major aspects of the problem and is well formulated, concise and well presented. There is little to add to the goals and objectives listed. Nevertheless, I would propose that the primary responsibility – and funding – for the program be returned to the USDA-Animal and Plant Health Inspection Services-Veterinary Services (USDA-APHIS-VS) rather than remain with FDA. The USDA-APHIS-VS was responsible for SE control from January 1990 to mid-1995. The USDA-APHIS-VS presently is the only Federal Agency with the field force capable of directly interacting with egg producers. It also administers the National Poultry Improvement Plan program for SE in all poultry breeding flocks in the US. The USDA-APHIS-VS has a cadre of some 30 Veterinary Medical Officers who are trained in poultry health and has offered to provide this expertise to the monitoring of egg quality assurance programs.

   The USDA-APHIS-VS also provides laboratory services for SE at the National Veterinary Services Laboratory (NVSL, Ames, Iowa) and is now involved in a certification program for other laboratories engaged in Salmonella diagnostics. The

USDA-APHIS-VS National Animal Health Monitoring System (Fort Collins, Colorado) has just completed a nation-wide survey of the egg layer industry. Finally, the USDA-APHIS-VS is the only Agency with the personnel and experience to conduct suitable epidemiologic investigations and tracebacks from human SE outbreaks in which eggs are implicated as the most probable food vehicle.

2. Although the FDA has statutory responsibility for shell eggs, it granted this authority to USDA from 1990-1995. Perhaps such authority should be legislatively granted to USDA, thereby adding eggs to meat and poultry as USDA responsibilities.

3. A number of different USDA agencies are concerned with SE (e.g., FSIS, AMS, APHIS, ARS). Their efforts would benefit from the appointment of a high-level SE Program Coordinator. This position – with appropriate authority and sufficient staff – could be charged with integrating program operations and avoiding duplication of efforts.

4. In addition to the national program operated by the United Egg Producers (the 5-Star Program), there are currently egg quality assurance (QA) programs in some 13 states, and more are on the way. The Action Plan proposes that there be mandatory national standards for these programs to provide a "level playing field". I believe that the egg industry is not yet ready for such an initiative and, in view of the rapidly declining SE rates, there is some question whether it is necessary at this time. It would take some years before all producers could comply with compulsory standards and their enforcement in the near future would force many out of business. Nevertheless, standards for a model QA program for eggs should be formulated and should be combined with a USDA Seal of Approval to provide some marketing advantage for participants. By itself, this market driven approach would encourage most producers to participate on a voluntary basis. As voluntary participation increases, a transition to a mandatory program might be feasible.

5. A crucial element in an acceptable QA program for eggs is the testing of layer flocks for SE and the diversion of eggs from test-positive flocks to pasteurization. Some 30% of all eggs produced in the US are now pasteurized for use as egg products. Many of the largest egg producers have their own in-line operations for routinely pasteurizing some of the eggs they produce.

   For egg producers who market only shell eggs in cartons, the detection of SE in their flocks – and the required diversion of eggs from these flocks – could mean financial ruin. Because SE does not ordinarily decrease production or increase morbidity/mortality in a layer flock, the control of SE is primarily to benefit public health. Consequently, the provision of financial assistance to producers who are forced to divert eggs from SE-positive flocks should be considered. This assistance

could be provided through the USDA-Agricultural Marketing Services, which already purchases quantities of egg products for various programs.

6. The responsibility for "investigating SE outbreaks, testing flocks, diverting eggs from SE-positive flocks, collecting flock data, and promoting better quality control" should be with the USDA-APHIS-VS. The Action Plan proposes that FDA carry out these functions. Yet, the FDA is not prepared to accomplish these tasks, and likely will cede responsibility for carrying out these tasks to the States.

7. The USDA should provide training in food safety to a large number of its field personnel. In particular, Veterinary Medical Officers (VMOs) should be targeted for this training. Upon completion of this training, the VMOs would be assigned to Departments of Health in various States to assist in the investigation of food-borne illnesses. State Health Departments are chronically in need of personnel and resources, and would welcome such assistance. Because the sources of practically all food-borne illnesses are related to various foods of animal origin, there is ample justification for the assignment of USDA VMOs to determine the sources of these pathogens. Furthermore, these professionals are ideally suited to help producers and processors prevent the transmission of food-borne pathogens to consumers.

8. Funding for research on the major food-borne pathogens should be increased. A small group of USDA specialists should be assigned to review and coordinate food safety research, award grants, and monitor progress and results.

9. Coordination between the NVSL, the Centers for Disease Control, and FDA laboratories should be increased. The NVSL should not charge for their laboratory diagnostic services when these services relate to pathogens of public health importance! The current practice of charging the public (and government) for Salmonella services substantially reduces the value of national statistics generated by the NVSL. In contrast, publicly funded laboratory services encourage unbiased reporting on the occurrence and distribution of Salmonella - including SE.

10. An SE Control Program Newsletter should be issued periodically to everyone directly concerned with SE in the US. From 1990-1995, I produced such a newsletter and it was widely referenced and appreciated.

11. To be inclusive, a number of other measures for egg safety are recommended.

    - The USDA regulation for the refrigeration of eggs should be aggressively enforced.
    - The use of pasteurized egg products should be made mandatory in certain institutions (e.g., nursing homes, hospitals, and chronic-care facilities).
    - The development and use of in-shell pasteurization should be Federally supported through grants or other subsidies.

- All egg cartons and cases should indicate the source of the eggs, and cartons should include a 21-day sell-by date, as well as a legend stating the need for proper refrigeration and cooking of eggs.
- The AMS egg-grading program should be available to all egg producers without cost, and should include a HACCP program for all egg processing facilities.
- The NPIP SE surveillance program for breeding flocks should continue to be actively supported by the USDA.
- The return, repackaging, and resale of outdated eggs should be prohibited.

I believe that the strategies for reducing human illnesses caused by SE in eggs are available. These strategies merit aggressive, action-oriented leadership to accomplish a reduction in human illnesses to negligible levels.

For your information, I am enclosing my comments in response to the Advance Notice for Public Rulemaking on "SE in Eggs", published in the Federal Register on May 18, 1998.

Sincerely,

John Mason

John Mason, DVM, MPH

FOOD SAFETY CONSULTANT SERVICES
JOHN MASON, DVM, MPH
301 East 64th Street
New York, New York 10021
(212) 628-1562

July 9, 1998

FSIS Docket Clerk
Docket No. 96-035A
Room 102
Cotton Annex Building
300 12th Street S.W.
Washington, D.C. 20250-3700

Dear Sirs:

This is in response to the request for comments in regard to the "Advance Notice of Proposed Rule Making" (ANPR), which was published in the Federal Register (Vol. 63. No. 96) on Tuesday, May 19, 1998, entitled "Salmonella Enteritidis in Eggs." My remarks are based on my experience as Director of the APHIS Salmonella Enteritidis Control Program from July, 1990 to November, 1994, and subsequent service as a Food Safety Consultant to the American Egg Board.

In order to reduce the food safety risks associated with shell eggs, I would propose the following:

1. The USDA should:

   a. Promulgate standards for egg quality assurance (QA) programs, which should include the best features of the QA programs in Pennsylvania and California, and should require microbiological testing and diversion of eggs from SE-positive flocks to pasteurization.

   b. Provide assistance, training and subsidies to agencies or groups wishing to start QA programs.

   c. Establish a "Seal of Approval" for acceptable QA programs.

   d. Provide services for monitoring and certification of QA programs, if they cannot be provided by State agencies.

   e. Establish a program to subsidize producers with SE-positive flocks who find it necessary to divert their eggs to pasteurization.

f. Provide laboratory services for QA programs, when necessary, including free Salmonella serotyping, the use of phage typing, and, where appropriate, the use of pulsed field gel electrophoresis.

g. Establish and operate, through the NVSL, a certification program for laboratories providing Salmonella diagnostic services.

h. Publish and distribute guidelines (Best Management Practices) for:

1. Biosecurity
2. Rodent and Pest Control
3. Cleaning and Disinfection
4. Molting
5. Egg Washing
6. Manure Management
7. Dead Bird Disposal
8. Spent Hen Disposal
9. Collection and Shipment of Samples for Microbiological Testing
10. Packing, Storage and Cooling of Eggs
11. Transport of Eggs to Market

i. Continue to support the NPIP program, particularly the SE monitoring program for breeding flocks.

j. Require stricter enforcement of sanitation standards and pasteurization practices at egg pasteurization plants.

k. Require "designated" tanker trucks, which should be properly sanitized, for the shipment of liquid eggs.

l. Promote the utilization of effective SE vaccines for pullets destined for egg layer flocks.

m. Continue to conduct spent hen surveys and surveys of liquid eggs for SE.

n. Carry on a nationwide surveillance program for SE. However, SE in layer flocks should not be treated as a reportable disease, with regulatory penalty, since this discourages testing for SE and the use of the laboratory results to divert eggs from SE-positive flocks to pasteurization voluntarily.

o. Carry out a comprehensive survey of the egg layer industry, now being planned by the USDA National Animal Health Monitoring System in Ft. Collins, as soon as possible.

p. Publish periodically a Newsletter, for persons and agencies concerned with egg safety, to report on the progress of the SE Control Program.

2. The USDA and the FDA, jointly, should:

a. Require, for the interstate shipment of eggs:

1. A 21-day sell-by date on egg cartons.
2. Indication on egg cases and cartons as to the source of the eggs.
3. Recommendations on egg cases and cartons for the proper handling of eggs.
4. Prohibition of resale of out-dated eggs as shell eggs, with their diversion to pasteurization plants.
5. Prohibition of resale of eggs from SE-positive flocks destined for pasteurization, as shell eggs.
6. Refrigeration of eggs after lay and processing so that the internal temperature will approximate 45°F or lower in 3-4 days, with maintenance at that temperature during storage, shipment and sale in markets.

b. Actively promote and support research on the prevention and control of SE.

c. Actively promote and support extensive educational and publicity programs for the improvement of food-handling practices.

d. Prohibit the export of eggs from known SE-positive flocks.

e. Promote the use of pasteurized eggs for recipes where raw or undercooked eggs are called for.

f. Promote the development of in-shell pasteurization procedures.

3. The FDA should:

a. Require the use of pasteurized eggs in Federal facilities such as prisons, hospitals, chronic care facilities and nursing homes, and should recommend their use in similar facilities not under Federal jurisdiction.

b. Limit tracebacks from human SE outbreaks to instances where:

1. There is sufficient epidemiological evidence that eggs were involved.
2. Cross-contamination or contamination by food handlers was not involved.
3. The eggs trace leads to a single flock or premises.

Eggs from SE-positive flocks detected as a result of a traceback should be diverted to pasteurization. Tracebacks should be used primarily to evaluate the operation of QA programs.

4. The following comments are specific references to the ANPR:

1. Salmonella typhimurium and Salmonella heidelberg are rarely found in the internal contents of shell eggs (pg. 27504).

2. A recent USDA risk assessment of SE in shell eggs estimates that SE contamination occurs in about 1 egg in 20,000, not 1 in 10,000, and that that frequency may result in 2.3 million SE-contaminated eggs annually, not 4.5 million (pg. 27505).

3. Because of the bacteriostatic action of egg albumen, where pracically all SE organisms are deposited before the affected egg is laid, it should not be necessary to rapidly chill eggs after lay, using carbon dioxide (pg. 27507).

4. Repackaging and rewashing of out-dated eggs should be prohibited. These eggs should be sent to "breaker" plants for pasteurization (pg. 27507).

5. All raw foods may contain harmful bacteria and consumers should be aware of the need to handle such foods properly. If shell egg cartons are to bear such a warning, then other raw foods should be marked in the same manner (pg. 27508).

6. Safe handling statements should be required on all egg cartons and egg cases (pg. 27509).

7. Egg producers should be enouraged to use HACCP-like QA programs, combining the best features of the Pennsylvania and the California programs, including microbiological testing and diversion of eggs from SE-positive flocks to pasteurization. These programs should be voluntary, not mandatory and producers participating in these programs should be able to benefit commercially through the use of a USDA Seal of Approval. This would encourage the great majority of egg producers to take part in approved QA programs. (pg. 27509).

8. The use of a mandatory sell-by date, which would vary depending on the temperature at which eggs were maintained, would be very difficult to enforce, and, in any case, would not be necessary if processors were given 3-4 days to bring the temperature of fresh shell eggs down to 45°F (pg. 27510). [1]

9. The education and training of food handlers, and particularly food-service managers, is crucial for effective SE-prevention. Practically all SE cases and outbreaks can be prevented by proper food-handling practices (pg. 27510).

10. Since at the present time it is not possible to guarantee that all raw shell eggs will be pathogen-free with the measures currently available (pg. 27506), any recommended preventive and control procedures for SE should remain voluntary (pg. 27510). Consumers would still have the choice of purchasing pasteurized eggs, or eggs coming from approved QA programs. Finally, it appears to me that if the risk of being exposed to SE is estimated at only one egg in 20,000, there is not enough justification to require that all eggs be pasteurized (pg. 27510).

Sincerely,

John Mason

John Mason

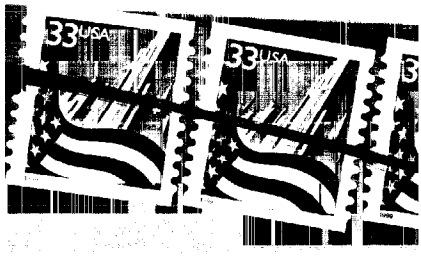
Enclosures: Pamphlets summarizing the Pennsylvania and California QA Programs.

---

[1]...on average, eggs laid at 99°F will achieve internal temperatures of 45° or less before the inherent resistance to yolk membrane breakdown is exhausted when the eggs are maintained at an ambient temperature of 45°F.

...there is an inherent delay - a time before SE growth can begin - of approximately 11 days at an internal temperature of 80°F, or 30 days at an internal temperature of 60°F. (from the Final Report - Salmonella Enteritidis Risk Assessment, Page 26).

Dr. John Mason
301 E. 64th St. (15B)
New York, N. Y. 10021



Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852